

REMARKS

Upon entry of this Amendment F and Response After RCE, claims 1, 2, 4-7, 9-12 and 14 will be pending. Claim 1 has been amended herein. Specifically, claim 1 has been amended to require that the gas-impermeable cover be formed of a plurality of portions. Support for this amendment can be found, for example, on page 4, lines 5-6; page 8 lines 18-21; and Figure 4 of the specification as filed. No new matter has been added by this amendment. Applicant respectfully requests reconsideration and allowance of all pending claims.

1. Rejection of Claim 1 under 35 U.S.C. § 112, Second Paragraph

Reconsideration is requested of the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In the current Office action, the Office maintains that the phrase "at least one [said] plurality of portions includes information related to heat that would be generated by the heat patch," is indefinite since it is vague with respect to the phrase "would be generated." Specifically, the Office asserts that if the user removed the portion including the information to control the air, no information would be generated. Again, Applicant respectfully disagrees with this assertion.

The information related to heat generated by the heat patch ("information") is adequately defined and clear in light of the specification. Initially, Applicant notes that the information on the plurality of portions is related to the heat that would

be generated if some or none of the portions are removed. The Office asserts that no "information" would be generated if the portion or portions including the information were removed. The Office, however, has misinterpreted claim 1, as removing the portions does not generate information, but, rather, generates **heat**. This is a significant difference, as it allows a user to remove the portions including the information related to generating heat while still understanding and retaining the information included thereon. As such, even if one removed the portion or portions that included the information related to heat generated by the heat patch, the user could still read the information on the detachable portion and understand the information relating to the heat generated by the removal of the portion.

Moreover, the portions include information related to heat generated by the heat patch when none, one, some or all of the portions are removed from the gas-permeable first layer.¹ For example, the information can be located on only one of the plurality of portions or on multiple portions.² The information may be indicated on the impermeable cover and may vary as long as the cover (or portions that form the cover) provides information relating to heat generated by the heat patch with and/or without removing the cover.³ The specification sets forth an example in which one or more of the portions may include alphanumeric information such as "REMOVING ONE COVER RAISES THE TEMPERATURE OF THIS HEAT PATCH TO 41 DEGREES C. & REMOVING BOTH

¹ See the instant Specification at page 10, lines 3-16.

² *Id.*

³ *Id.*, at page 11, lines 2-8.

COVERS RAISES THE TEMPERATURE OF THIS HEAT PATCH TO 44 DEGREES C."⁴ One skilled in the art, reading the claims in light of the specification, would easily ascertain the information that is being provided; that is, that the information is explaining what will happen to the temperature of the patch when none, one or more portions of the cover is removed.

The Office further states that if the patch contained only one cover, and that cover were to be removed by the user, that the user would have no information. Applicant again points out that even if only one portion discloses the information, and this portion is removed by the user, the user has already read the information, retained the knowledge, and proceeded accordingly. That is, the user knows beforehand what will occur after the portion is removed. And, as noted above, the information is still on the detachable portion even though it has been removed. Thus, even though in an exemplary embodiment a single portion may disclose the information, the information disclosed conveys to the user the heat generated by the heat patch when none, one or more of the portions are removed from the gas-permeable first layer. As such, in a situation where there is more than one portion, and only one portion discloses information, even if the user decides to remove the portion with the information, the portion with the information has supplied the user with the requisite knowledge to remove the remaining portions when/if the user deems necessary while fully comprehending the effects of their removal. Accordingly, it is clear to one skilled in the art reading the present application

⁴ *Id.*, at page 10, lines 20-24.

that any one portion or more than one portion can be removed prior to use and the user can easily ascertain the information related to heat that would be generated; that is, even if the portion removed includes the information related to heat that would be generated, one skilled in the art would be clear as to what information is provided.

In the current Office action, the Office further asserts that if the user decides not to remove any portion, then the user would not have any information. Applicant respectfully disagrees. Specifically, as disclosed in the specification, any type of information, including information related to the steady-state temperature of the heat patch with and/or without the cover on the heat patch may be indicated on the cover.⁵ Thus, as further disclosed in the specification, and, as noted above, each of the portions can include information related to heat generated by the patch when none, one, some or all of the portions are removed from the gas-permeable first layer. Again, contrary to the Office's assertion, it is not information that is generated by the removal of one of the portions, but, rather, heat that is generated. As such, a user of the heat patch would readily understand the information relating to the heat patch even if none of the portions were removed.

Accordingly, claim 1 is definite under 35 U.S.C. § 112, second paragraph.

⁵ *Id.* at page 10, lines 7-9.

2. Rejection of Claims 1-2 and 4-7 under 35 U.S.C. § 103(a)⁶

Reconsideration is requested of the rejection of claims 1, 2, and 4-7 under 35 U.S.C. § 103(a) as being unpatentable over Zhang, et al. (U.S. Patent No. 5,658,583) in view of Usui (U.S. Patent No. 5,879,378) and further in view of DeCarlo, et al. (U.S. Patent No. 6,409,748).

Claim 1, as amended, is directed to a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer such that a perimeter of the gas-permeable first layer is bonded to a perimeter of the second layer. The gas-permeable first layer includes an inner surface and an outer surface, wherein said entire first layer is gas-permeable. The heat patch also includes a heating composition inside the enclosure, wherein the heating composition is capable of generating heat when a gas is received through the gas-permeable first layer. In addition, the heat patch includes a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer. The gas-impermeable cover is formed of a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, wherein at least one of said plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said

⁶Applicant again notes that in paragraph 4 of the Office Action, the Office has rejected claims 1-2 and 4-7 under 35 U.S.C. 102(b) as being anticipated by Zhang, et al. in view of Usui and DeCarlo, et al. Applicant again respectfully asserts that this was a typographical error in that the Office intended to reject claims 1-2 and 4-7 under 35 U.S.C. 103(a) as being obvious in view of the cited references as support by the 103(a) language in paragraph 4 of the Office Action. Applicant requests the Office to contact

gas-permeable first layer.

Zhang, et al. disclose an apparatus, product formulation, and method for improved dermal penetration of pharmaceuticals. The apparatus includes a drug formulation reservoir and a heat-generating chamber separated by a first non-permeable wall. The reservoir and chamber are formed in or supported by a housing which may be formed completely or partially of a thermal insulating material. The heat generating chamber (e.g., heating element) includes means for generating controlled heat, and preferably, the heat generating means is a chemical composition made of carbon, iron powder, water, and/or salt which is activated upon contact with air. The heat generation chamber is capped by a structure which has substantially non-air permeable areas such as areas preferably formed with good thermal insulating material, such as closed-cell foam tapes, and openings or areas comprising material with desired permeability to air. Alternatively, the entire structure may be made of semipermeable membrane with desired air permeability. The entire device is stored in an air-tight packaging, or container, or a removable barrier is employed to cover the semipermeable membrane(s) or openings to prevent premature activation of the heat-generating medium. One means to reduce the air flow rate to the heat-generating medium is to place a few small pieces of tape in a convenient place on the device. The tape can be peeled off and placed on top of the opening(s), the

Applicant's representative, Mr. Christopher M. Goff, if this assumption is incorrect.

semipermeable membrane area(s) or the semipermeable membrane surface to reduce air flow and thus temperature.

Significantly, as recognized by the Office, Zhang, et al. fail to disclose a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer such that **a perimeter of the gas-permeable first layer is bonded to a perimeter of the second layer** as is required in Applicant's claim 1. As further noted by the Office, Zhang, et al. do not disclose a heat patch having a plurality of portions with **information related to heat generated by the heat patch when one or more portions are removed from the gas-permeable first layer**. Moreover, Zhang, et al. fail to teach or suggest a heat patch including a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer, wherein the gas-impermeable cover **is formed of a plurality of portions detachably mounted** to the outer surface of the gas-permeable first layer.

The Office asserts at page 4 of the instant Office action that "Zhang et al. substantially discloses the invention as claimed, further, Zhang et al. discloses a heat patch gas-impermeable cover [that] includes a plurality of portions (31 shown in figure 1 shown to be detachably attached as disclosed in column 11, lines 7-11" Applicant respectfully disagrees and submits that the "cover", or structure (22), in Zhang, et al. is not formed of a plurality of portions as is recited in Applicant's claim 1. Rather, the cover in Zhang, et al. is a single cover that includes substantially non-air permeable areas (24) and openings or areas (26) with desired

permeability to air, neither of which are detachably mounted to the cover, wherein the openings or areas (26) may be covered during use by a piece of tape initially located on a different portion of the patch. The "cover" of Zhang, et al. merely has the capability to accept the pieces of tape that are positioned on the "convenient place" referred to by the Office during use of the patch in order to regulate the temperature of the patch. As such, in contrast to the cover in Applicant's claim 1, the pieces of tape in Zhang, et al. are in a completely separate and distinct location from the cover in Zhang, et al., and, subsequently, the cover in Zhang, et al. is not formed of a plurality of portions.

Moreover, Applicant respectfully disagrees with the Office's assertion that reference numeral "31" in Zhang, et al. describes a "plurality of portions." Specifically, nowhere in Zhang, et al. do they ever describe what reference numeral "31" is referring to. In fact, the only instance in which reference numeral 31 appears in Zhang, et al. is in figure 1 of the drawings. In column 5, Zhang, et al. describes the pharmaceutical administering device of Figure 1. Significantly, however, Zhang, et al. do not discuss reference numeral 31, let alone a "plurality of portions" as suggested by the Office. Accordingly, Zhang, et al. do not disclose the invention as claimed.

Further, in the "Response to Arguments" section on page 10 of the current final Office action, the Office asserts that "Applicant does not claim that the plurality of portion[s] are

detachably placed on the heat patch."⁷ Applicant respectfully disagrees, as the language of claim 1 specifically states that the gas-impermeable cover is detachably mounted to the outer surface of the gas-permeable first layer; and, further, that said gas-impermeable cover is formed of a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer. Applicant asserts that the Office is simply incorrect in this regard.

On page 11 of the current final Office action, the Office asserts that the originally filed specification and drawings do not support Applicant's argument that a cover is formed of a plurality of portions. Applicant respectfully disagrees. As indicated on the Patent Application Information Retrieval (PAIR) system, on August 27, 2003, Applicant filed Figures 1-8 along with the instant application. Specifically, the plurality of portions are depicted as reference numbers 28A, 28B, 38A, 38B, 48A, 48B, 48C, 48D, 58A and 58B.⁸ For example, on page 8, lines 18-21 of the specification and in Figure 4, the specification and Figure 4 detail that the gas-impermeable cover (27) is formed of the plurality of portions (28A and 28B). As indicated above, in claim 1 and in the Figures 3-8, the gas-impermeable cover is formed of the plurality of portions, which are detachably mounted to the outer surface of the gas-permeable first layer. As such, Applicant submits that Applicant's argument is not narrower than what is claimed, and that the

⁷ See, page 10 of the instant Office action.

⁸ See Figures 3-8 and page 8, line 18 - page 10, line 16 of the instant specification.

originally filed specification and drawings fully support the cover being formed of a plurality of portions.

Recognizing that Zhang, et al. fail to teach or suggest each and every limitation of Applicant's claim 1, the Office attempts to combine Usui and DeCarlo, et al. with Zhang, et al. in order to arrive at each and every element of Applicant's claim 1 as required by the M.P.E.P. for a determination of a *prima facie* case of obviousness.

Usui discloses an exothermic device that has an exothermic composition enclosed in a flat pouch formed of a film or sheet. The exothermic composition is formed in two layers including an exothermic reaction layer and a single reaction auxiliary layer. The exothermic reaction layer includes iron powder and the auxiliary layer includes other ingredients. Specifically, a known exothermic composition may be used, which includes, for example, a metal powder, carbon powder, a metallic chloride, water, a water retainer, an inhibitor, a surface active agent, and an anti-foaming agent. The pouch has at least one surface formed of a gas-permeable flat film or sheet in order to allow the exothermic composition enclosed therein to contact oxygen in the atmosphere. Exemplary materials for use as the gas-permeable flat film or sheet include, for example, polymeric materials such as polyethylene, polypropylene, polyamide, polyester, polyvinyl chloride, polyvinylidene chloride, polyurethane, polystyrene, saponified ethylene-vinyl acetate copolymer and ethylene-vinyl acetate copolymer; paper; clothes; and the like. In one particular embodiment, the pouch is formed by placing a gas-tight backing film over the exothermic

composition placed on a single gas-permeable film and heat-sealing the peripheries of the gas-permeable film and the backing film.

DeCarlo, et al. disclose a heating pad capable of rapid initial heat transfer to a heating pad member by means of a removable gel pack member which is releasably attached to the heating pad member. The removable gel pack member is releasably attached to the second layer of the heating pad cover and comprises a heat-retentive gel which is heated to a predetermined temperature prior to attachment. In one embodiment, when the gel pack is placed in substantial contact with an anatomical portion of subject in need of heat therapy, heat is transferred to the subject through the interface formed by the inner layer of the pad. The inner and outer sheets of the pad are sealed along the edges by means known in the art. Additionally, the gel pad member may have a temperature indicator, such as a tape containing an indicating temperature-sensitive liquid crystal substance, which visually indicates to the user that the gel pack member has been heated to an excessive temperature for normal use in a heating pad.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. § 2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere

conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."⁹ The Court in KSR International further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited references fail to show each and every limitation of Applicant's invention and there is no apparent reason for one

⁹ *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

skilled in the art to modify and/or combine the references to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicant's claimed combinations.

Specifically, no where do the cited references teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to the outer surface of a gas-permeable first layer, wherein the gas-impermeable cover is formed of a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of the plurality of portions includes information related to heat that would be generated by the heat patch when one or more of the plurality of portions is removed from the gas-permeable first layer. At best, Zhang, et al. disclose a layer that may be partially covered to reduce air flow to the heat-generating medium, however, as noted above, Zhang, et al. do not disclose a cover that **is formed of** a plurality of portions **detachably mounted** to a gas-permeable layer¹⁰ to accomplish the result as required in Applicant's claim 1. Rather, as noted above, Zhang, et al. disclose pieces of tape placed in a convenient place on the device that are removed from the first location and subsequently placed over portions of the cover (which is a second, separate location) to reduce air flow through the cover. Furthermore, although Zhang, et al. describe that the device may employ a removable barrier over the semipermeable membrane(s) or openings to prevent premature activation of the heat-generating medium, Zhang, et al. do not disclose that the pieces of tape

¹⁰ See the instant Specification at page 4, lines 5-6 and lines 21-22.

used to reduce the air flow are part of, or, included in, the disclosed removable barrier. In contrast to the present invention, where removable portions form the cover and are removed to expose a portion of the gas-permeable first layer, the pieces of tape in Zhang, et al. are removed from another portion of the device and placed over the cover such that the exposure of the gas-permeable layer is limited. The Usui and DeCarlo, et al. references fail to overcome these shortcomings as the Usui reference merely teaches an exothermic device that has an exothermic composition enclosed in a flat pouch formed of a film or sheet, and the DeCarlo, et al. reference merely teaches a heating pad with a gel pad member that optionally may have a temperature indicator, which indicates to the user that the gel pad member has been heated to an excessive amount. As such, none of the cited references, alone or in combination, teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to an outer surface of a gas-permeable first layer, wherein the gas-impermeable cover is formed of a plurality of portions, which are detachably mounted to the outer surface of the gas-permeable first layer.

Furthermore, no where in any of the cited references is it taught or suggested that at least one of said plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer. At best, the DeCarlo, et al. reference discloses a liquid crystal temperature-indicator that visually alerts the user that the pad has been excessively heated. However, as noted above, DeCarlo,

et al. do not disclose at least one of a plurality of portions that includes information related to heat generated by the heat patch when one or more of the plurality of portions is removed from the gas-permeable first layer. Applicant initially submits that the optional temperature indicator of DeCarlo, et al. is not attached to a gas-permeable first layer. Further, the temperature indicator in DeCarlo, et al. does not provide information as to what happens when the indicator is removed.

In the current final Office action, the Office asserts that the tape in DeCarlo, et al. is removable "as all tapes are." Applicant respectfully disagrees. Specifically, in contrast to the present invention, the indicator in DeCarlo, et al. is not meant to be removed. A user of the heating pad in DeCarlo, et al. would want the indicator to remain on the heating pad, so that the user will know whether or not the pad has been heated excessively. If a user were to remove the indicator disclosed in DeCarlo, et al. from the heating pad, the indicator would not be capable of performing its described and intended function because removal of the indicator would prohibit the indicator from indicating the actual temperature of the heating pad. As such, contrary to the Office's assertion, in order for the tape in DeCarlo, et al. to function for its intended purpose, the tape in DeCarlo, et al. is not removable.

The Office re-asserts on pages 4-5 of the current final office action that "with respect to the limitation of 'and wherein at least one of plurality of portions includes information related to heat generated by the heat patch when one or more of plurality of portions removed from said gas-permeable

first layer' has been treated as an intended use recitation." Applicant again respectfully disagrees. M.P.E.P. §2114, citing In re Schreiber, 128 F.3d 1473, 1477-78, states that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. Further, §2114 states that "[a]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469. In this case, the recitation "wherein at least one of said plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer" is in fact a positively claimed structural limitation and does not merely recite the intended function or use of the invention. Although information included in certain positions of the portion may not be visible until the time at which the portion is removed, the information is nonetheless present on one or more of the plurality of portions at all times, as it is a structural characteristic of the heat patch. The recitation "related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed" refers to the type of information that is included on one of the portions. The portion does not need to actually be removed for the portion to structurally include the information. Again, Applicant notes that contrary to the Office's assertion, it is not information that is generated by the removal of the portions, but, rather, heat that is generated by removal of the portions. The

information is thus a structural limitation that relates to the heat that would be generated upon removal of none, one, or more of the portions. Accordingly, Applicant submits that the above-mentioned limitation is not an intended use limitation, but, rather, imparts a structural characteristic to the claimed invention that is not shown in any of the cited references.

Moreover, even if the DeCarlo, et al. reference taught the limitation of Applicant's requiring information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer (which, as noted above, Applicant respectfully asserts that the reference does not), there is no reason to combine the DeCarlo, et al. reference with Zhang, et al. and Usui. Particularly, the DeCarlo, et al. reference is directed to a completely different mechanism of heating from that of Zhang, et al. and Usui. More specifically, as described above, Zhang, et al. and Usui (and Applicant's claimed invention) require an exothermic reaction to generate heat. By contrast, DeCarlo, et al. teach a heat-retentive gel that is heated to a predetermined temperature prior to use. As such, there is simply no apparent reason for one skilled in the art, reading the Zhang, et al. and Usui references to look to DeCarlo, et al. for possible combination.

In the current final Office action, on page 10, the Office asserts that there would be reason to combine the cited references because they are "related in examiner's opinion to be analogous art." The Office, however, does not address Applicant's argument that regardless of the field of art of the

references, there is simply no reason to combine them. Moreover, even if the references are "analogous art," Applicant notes that there are numerous analogous art references in the field of temperature changing patches. As such, why would one having ordinary skill in the art choose DeCarlo, et al., from all of the numerous analogous art references, to combine with the cited references, particularly when DeCarlo, et al. is directed to a completely separate type of heating as compared to the cited references, as well as the instant Application? It simply cannot be stated that it would be obvious to do so.

Based on the foregoing, none of the cited references, alone or in combination, teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to an outer surface of a gas-permeable first layer, wherein the gas-impermeable cover is formed of a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer as is recited in Applicant's claim 1. As there is no teaching or suggestion of each and every limitation, and further, there is no reasoning provided to one of ordinary skill in the art to modify the heat patch cover to arrive at the heat patch as required in claim 1, claim 1 is patentable over the cited references.

Claims 2 and 4-7 are depend from claim 1 and are patentable over the cited references for the same reasons as claim 1 set

forth above, as well as for the additional elements they require.

3. Rejection of Claims 9-12 under 35 U.S.C. § 103(a)

Reconsideration is requested of the rejection of claims 9-12 under 35 U.S.C. § 103(a) as being unpatentable over Zhang, et al. (U.S. Patent No. 5,658,583), Usui (U.S. Patent No. 5,879,378), and DeCarlo, et al. (U.S. Patent No. 6,409,748) in view of Kuratomi, et al. (U.S. Patent No. 4,747,841).

Claim 1, from which claims 9-12 depend, is discussed above.

The Zhang, et al., Usui, and DeCarlo, et al. references are discussed above. Significantly, as discussed above, the Zhang, et al., Usui, and DeCarlo, et al. references fail to teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to the outer surface of a gas-permeable first layer, wherein the gas-impermeable cover is formed of a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer. Furthermore, the above cited references fail to provide a reasoning for modifying and/or combining the references to arrive at each and every limitation of Applicant's claimed combination. Kuratomi, et al. fail to overcome the above shortcomings.

Specifically, Kuratomi, et al. disclose a method and apparatus for moxibustion comprising feeding air to a heat

generating composition in contact with an herb material comprising moxa. The heat generating composition comprises pyrogen and the herb material is located adjacent to a skin surface. The pyrogen used comprises a heat generating composition consisting of iron powder, carbon, cellulose, chloride, and water. The air causes the pyrogen to generate heat by oxidation, whereby the herb material is heated and vaporized and the generated heat and vapor act on the skin, causing moxibustion effect. An oxygen-impermeable package body is used to pack the pyrogen while not in use, and a gas-permeable internal package is used to house the pyrogen. The internal package may be formed of woven fabric of synthetic resin, cotton, etc. The exterior of the internal package is covered with the external package formed of a non-permeable material such as a synthetic resin film or thin plate, preventing the pyrogen from contacting the air. The pyrogen can be adjusted for the desired heat generation time and temperature by adjusting the composition of the material or the ventilating structure. Temperatures of 65°C are common at the heat generation source while the temperature at the point of contact with human skin is about 40°C to about 45°C.

Significantly, Kuratomi, et al., as with the Zhang, et al., Usui, and DeCarlo, et al. references, fail to teach or suggest a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer, a heating composition inside the enclosure, and a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer, wherein the gas-impermeable cover is formed of a plurality of

portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer.

As the references, alone or in combination, fail to teach or suggest all of the elements of claim 1 and, further, there is no motivation or apparent reason to modify and/or combine the cited references to arrive at each and every limitation of Applicant's claim 1, claim 1 is patentable over the cited references.

Claims 9-12 depend from claim 1 and are thus patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

4. Rejection of Claim 14 under 35 U.S.C. § 103(a)

Reconsideration is requested of the rejection of claim 14 under 35 U.S.C. § 103(a) as being unpatentable over Zhang, et al. (U.S. Patent No. 5,658,583), Usui (U.S. Patent No. 5,879,378), and DeCarlo, et al. (U.S. Patent No. 6,409,748) further in view of Christy, et al. (U.S. Patent No. 5,786,578)¹¹.

Claim 1, from which claim 14 depends, is discussed above.

¹¹ Applicant notes that in the current Office action, the Office has again listed Christy, et al. as having a U.S. Patent number of 5,692,238. Said number, however, is the U.S. Patent number of Watson, Jr., which was a reference cited in a previous Office action. Applicant respectfully asserts that this was a typographical error in that the Office intended to cite Christy, et al. as having the U.S. Patent number of 5,786,578.

The Zhang, et al., Usui, and DeCarlo, et al. references are discussed above. Significantly, as discussed above, the Zhang, et al., Usui, and DeCarlo, et al. references fail to teach or suggest a heat patch comprising a gas-impermeable cover that is detachably mounted to the outer surface of a gas-permeable first layer, wherein the gas-impermeable cover is formed of a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer. Furthermore, the above cited references fail to provide a reasoning for modifying and/or combining the references to arrive at each and every limitation of Applicant's claimed combination. Christy, et al. fail to overcome the above shortcomings.

Specifically, Christy, et al. disclose a microwave-heatable therapeutic exercise putty having at least one transparent wall. A thermochromic heat sensitive semiconductor material is affixed to the transparent wall in intimate heat transfer contact with the putty mass. The thermochromic material provides a visual first indication through the transparent wall when the putty mass has been microwave-heated to a heat exercise therapy acceptable temperature range of about 40 to about 47 degrees C. and a visual second indication through the transparent wall when the putty mass has been microwave heated to a temperature range of about 54 to about 60 degrees C. or above. In one embodiment of the invention, a heat sensitive strip, label, membrane or

coating, which includes a thermochromic semiconductor material is affixed to the inside of the bottom wall of the base portion of the container, and varies in transparency and color in response to various temperature levels to which the material is exposed.

Significantly, however, Christy, et al., as with the Zhang, et al, Usui, and DeCarlo, et al. references, fail to teach or suggest a heat patch comprising an enclosure that includes a gas-permeable first layer and a second layer, a heating composition inside the enclosure, and a gas-impermeable cover that is detachably mounted to the outer surface of the gas-permeable first layer, wherein the gas-impermeable cover is formed of a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer, and wherein at least one of said plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer.

As the references, alone or in combination, fail to teach or suggest all of the elements of claim 1 and, further, there is no motivation or apparent reason to modify and/or combine the cited references to arrive at each and every limitation of Applicant's claim 1, claim 1 is patentable over the cited references.

Claim 14 depends from claim 1 and is thus patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional elements it requires.

In addition to the recitations in claim 1, claim 14 further requires that at least some of the plurality of portions are different colors, the colors supplying the information related to heat generated by the heat patch when one or more of the plurality of portions is removed from the gas-permeable first layer. Applicant notes, as is addressed above, that the thermochromic semiconductor material disclosed in Christy, et al. can vary in transparency and color in response to various temperature levels. Applicant submits that the semiconductor material is not attached to a gas-permeable first layer as is recited in Applicant's claims. In addition, the semiconductor material disclosed in Christy, et al. is not meant to be removed from the putty container such that the semiconductor material is not detachably connected to the garment as is required of the plurality of portions of Applicant's claim 14. As such, claim 14 is patentable over the cited references for these additional reasons, as well as for the reasons set forth above for claim 1.

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CONCLUSION

In light of the foregoing, Applicant requests withdrawal of the rejections of claims 1, 2, 4-7, 9-13, and 14 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

/Christopher M. Goff/

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